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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/071,722

02/07/2002

Andrew J.S. Evans

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10/18/2006

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BOSTON, MA 02109

EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT

PAPER NUMBER

3771

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,722

Applicant(s)

EVANS ET AL.

Examiner

Annette F. Dixon

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6, 9, 15-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Great Britain Patent Specification Number 1,499,807 to Ring.

Regarding claims 1 and 19, Ring discloses an orthosis (see Figure 1) comprising an orthotic strut component (any of 2, 3, 5) for an orthosis comprising the combination of a ductile metallic tube (21) having a transverse cross-section of elongate shape (see Figure 2) and an internal core (22) of substantially uncured pre-impregnated fibre and plastics composite material within the tube (again, see Figure 2), the fibers of the core being substantially unidirectional and running lengthwise of the tube (page 2, lines 28-36; Ring defines the fibers as being "tows". See definition of "tow", which defines "a bundle of untwisted natural or man-made fibers").

Ring discloses each and every structural element of the strut as set forth in claim

1. Ring discloses a tube having an internal core of pre-impregnated fibre and plastic composite material wherein the fibers are substantially unidirectional and run lengthwise of the sheet, but Ring is silent as to the method of making internal core. The claimed phrase "rolled-up, substantially uncured sheet" is being treated as a product by process limitation; that is, that the internal core is made by rolling up a sheet of material.

As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps (i.e., claim 1 implies the structural requirement that the fibers be unidirectional and run lengthwise in the tube, but does not require the internal core be a rolled-up sheet). Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Ring does not specify the claimed process used to make the plastic channels, it appears that the product in Ring would be the same or similar as that claimed; especially since both applicant's product and the prior art product include an internal core of fibre and plastic composite, with substantially unidirectional fibers running lengthwise through the core.

Regarding claim 2, the tube is made of annealed aluminum alloy.

Regarding claims 3, 5 and 18, the cross-section of the tube is of an oblong-shape having substantially straight sides and rounded ends.

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Regarding claims 4 and 5, the cross-sections of the strut and tube are substantially constant over the major part of the length of the strut component (see Figure 1 for example).

Regarding claim 9, after the strut is fitted to a user, the core is cured (lines 90-92).

Regarding claim 16, the internal cross-sectional area of the tube is substantially fully occupied by the internal core (see Figure 2).

Regarding claim 20, Ring discloses that the struts can be shaped to fit the user (i.e., "bent"; see lines 84-86).

Ring discloses the invention substantially as claimed, however, Ring does not specify the dimensions of the strut.

At the time the invention was made, however, it would have been an obvious matter of design choice to a person of ordinary skill in the art of orthotics to have provided the struts with the claimed length, wall thickness, internal circumference (and necessarily *K* value), cross-sectional ratio and thickness, because Applicant has not disclosed that such dimensions provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Ring's orthotic struts, and Applicant's invention, to perform equally well with either the dimensions shown by Ring or the claimed dimensions because both dimensions would perform the same function of securing to the lower leg of a user and providing support for the lower limbs. It would have been obvious to one skilled in the art of orthotics, at the time the invention was made, to have discovered the ideal

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dimensions of the struts, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Therefore, it would have been prima facie obvious to modify Ring to obtain the invention as specified in claims 1-6, 9, 15-16 and 18-20 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Ring.

3. Claims 7, 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ring in view of Japanese Patent Number 5-337966 ('966; in accordance with its English-language abstract).

Ring discloses the previously described orthosis and orthotic strut component, wherein the strut comprises an aluminum tube having a cross-section of elongate shape and an internal core of uncured plastics and fibre composite material. Ring does not specify an expansion agent within the plastics and fibre composite material.

'966 discloses a method of forming a plastics and fibre composite material into a desired shape. A plastic and fibre composite material is impregnated with an uncured hardenable resin and placed within a mold. '966 specifies that an inner kernel of a heat-activated expansion agent extends through the composite material, wherein the expansion agent is a foaming agent that includes an epoxy resin, to enlarge the composite material into the shape desired (i.e., by forcing the material into the shape of the mold).

It would have been obvious to one skilled in the art at the time the invention was made to have provided the orthosis and orthotic strut disclosed by Ring, wherein an inner kernel of expansion agent is located within the plastic and fibre composite material, as taught by '966, to enlarge the composite material into the exact shape desired.

Response to Arguments

The amendment filed on August 3, 2006, has been entered. Examiner acknowledges that Claims 1-9 and 15-21 are pending in this application, with claim 21 having been added.

Applicant's arguments filed August 3, 2006 have been fully considered but they are not persuasive. Applicant asserts that "rolled-up" is not a process or manner by which the orthotic strut component has been produced, but rather a structural feature. However, the very essence of a producing an element that has the structural characteristics of being "rolled-up" involves the process of manipulating the element into the recited orientation. Further, Ring discloses the fibers to be "tows" of carbon fibers (line 33, page 2). As defined by the Oxford Online Dictionary (copy provided), a tow is considered to be a bundle of untwisted fibers. Based on a broad, reasonable interpretation of the term "tow", Ring does in fact disclose the implied structural requirement that the fibers be unidirectional and run lengthwise in the tube. Ring does not disclose that the internal core be made by rolling up a sheet of uncured fibre and plastic composite material, however, this is not required because the limitation is a

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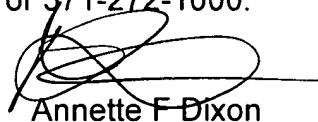
product-by-process limitation, which does not imply any structure to the claim over that which is met by Ring. Therefore the rejection of Claims 1-9 and 15-20 in the Office Action, mailed February 7, 2006, has been maintained.

Conclusion

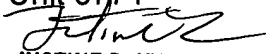
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Annette F Dixon
Examiner
Art Unit 3771



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10/16/06